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08/721447

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/721,447 09/27/96 PINSKY

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HM11/0720

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NEW YORK NY 10036

EXAMINER

CANCEL  
ART UNIT PAPER NUMBER

1644

DATE MAILED:

10

07/20/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/4/98

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-45 is/are pending in the application.

Of the above, claim(s) 1-28, 39-45 is/are withdrawn from consideration.

☐ Claim(s) is/are allowed.

☒ Claim(s) 29-38 is/are rejected.

☐ Claim(s) is/are objected to.

☐ Claims are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received:

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 9

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

### DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1642, Group 1640, Technology Center 1600.

2. Applicant's amendment, filed 5/4/98 (Paper No. 9), is acknowledged.  
Claim 29 has been amended.

Claims 29-38 are under consideration in the instant application.

Claims 1-28 and 39-45 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Applicant acknowledges that the election of Group III was made with traverse in Paper No. 6.

3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 5/4/98 (Paper No. 9). The rejections of record can be found in the previous Office Action (Paper No. 7).

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention, including the use of Factor IX.

Applicant will amend the title, if necessary, upon the indication of allowable subject matter.

5. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 previously sent in Paper No. 7. Applicant is reminded to change the Brief Description of the Drawings in accordance with these changes.

Applicant will provide formal drawings upon the indication of allowable subject matter.

6. The specification is objected to and claim 33 is rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention essentially for the reasons set forth in Paper No. 7.

Applicant's arguments in conjunction with Exhibits A-C, filed 5/4/98 (Paper No. 9), have been fully considered but are not found convincing.

Applicant argues that the use of aerosol, oral, topical carriers for delivering therapeutic effective amounts of compositions are known in the art. With respect to treating disorders associated with the claimed disorders, applicant provides Exhibits A-C.

However, the nature of pharmaceutical compositions relied upon by these Exhibits differ dramatically in their pharmacokinetic properties than the factor IX. Applicant's evidence does not rely upon proteins such as factor IX, which would require the appropriate conformation and, in turn, access to the vascular system to be therapeutically effective. Applicant has not provided sufficient guidance and direction nor objective evidence that the skilled artisan can deliver a therapeutic effective amount of a protein, even a chemically inactivated protein, such as the instant factor IX in an aerosol, oral or topical carrier in treating ischemic disorders. Ischemia comprising treating vascular disorders and it would not be predictable that one could deliver a therapeutic effect amount in such disorders other than intravascular routes of administration. In the absence of objective evidence to the contrary; aerosol, oral and topical carriers and means of delivery for proteins such as the instant factor IX are not enabled for treating ischemia.

Applicant's arguments are not found persuasive.

7. Applicant's amended claims and arguments, filed 5/4/98 (Paper No. 9) have obviated the previous rejection under 35 U.S.C. § 102(b) as being anticipated by Moller et al. (CA 2,141,642), as it would apply to the instant claims.

8. Claims 29-38 are rejected under 35 U.S.C. § 103 as being unpatentable over Moller et al. (CA 2,141,642) in view of standard methods of inactivation as acknowledged on page 17 of the instant specification and in view of known ischemic disorders as acknowledged on page 16 of the instant specification essentially for the reasons of record set forth in Paper No. 7.

Applicant's arguments, filed 5/4/98 (Paper No. 9), have been fully considered but are not found convincing. Applicant argues that the amended claim 29 obviates the previous rejection. Applicant argues that Moller et al. teaches away from the use of chemically modified factor IX. Applicant relies upon pages 4-5 and 10 of Moller et al., which discloses that "proteolytic fragments are not modified and that "fragments shouldn't be chemically modified" and that their invention is an "avoidance of chemical modification of factor IX fragments.

However, the instant claims are not drawn to chemically modified fragments, but rather chemically inactivated factor IXa. As known in the art at the time the invention was made and disclosed in this reference, factor IX has an important role in hemostasis. The key to Moller's invention was determining fragments that do not have coagulation activity and therefore avoid the use of chemical inactivation. However, the instant claims are not drawn to the small fragments that do not have coagulation activity relied upon by Moller. In contrast, the instant factor IXa was known and was expected to have coagulation activity. Therefore, to employ the instant factor IXa as an antagonist, the ordinary artisan would have recognized the requirement to inactivate said factor IXa; otherwise it would have had coagulation activity. Such coagulation activity runs contrary to the desired inhibitory effects. Furthermore, even though Moller's invention was drawn to determining certain fragments with inhibitory effects, this does not discount that the ordinary artisan was motivated to antagonize thrombosis with factor IX-derived fragments. To avoid the coagulation activity of such fragments, such as factor IXa; it would have been obvious and necessary to inactivate such coagulation properties to be used as an inhibitory agent. Such inactivation including chemical inactivation was known and practiced at the time the invention was made, as set forth in the last Office Action and acknowledged by applicant.

Applicant's arguments are not found persuasive.

9. No claim is allowed.

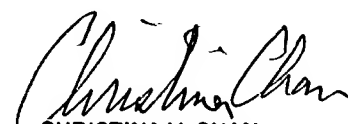
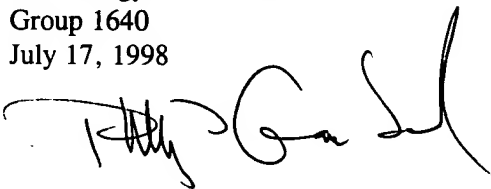
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, Ph.D.  
Patent Examiner  
Technology Center 1600  
Group 1640  
July 17, 1998



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GROUP 1800-1640